REMARKS/ARGUMENT

Amendments to the Claims

Claims 11 and 22 have been amended and substantially narrowed by incorporating the amount of the glycyrrhetic antibacterial agent from Claim 15, a zinc salt of glycyrrhetic acid as the "glycyrrhetic antibacterial agent" from Claims 12 and 14, benzoyl peroxide as an additional antibacterial agent from Claim 16 and the Specification at page 4, line 19, and the amount of benzoyl peroxide in the preparation from the Specification at page 4, line 25, into them.

Claims 16 and 27 have been amended by substituting salicylic acid-N-alkylamides from the Specification at page 26, line 8, in place of "derivatives" of salicylic acid.

Claims 18 and 29 have been amended and narrowed by the substitution of a glycyrrhetic acid zinc salt in place of "glycyrrhetic antibacterial agent".

Claims 19 and 30 have been amended, consistent with the amendments to Claims 11 and 22, by the use of "glycyrrhetic acid zinc salt" and "benzoyl peroxide".

Claim 20 has been amended to depend on the preparation from Claim 11, consistent with the incorporation of a zinc salt of glycyrrhetic acid from now-canceled Claim 12 into Claim 11.

The remaining amendments to the Claims have been made for grammatical, stylistic and/or clarifying purposes, without substantively adding to or deleting from the Claims in any way.

Accordingly, Applicants submit that amendments to the Claims are fully supported by the original Specification and Claims and add no new matter to the Application. Entry of

these amendments and continued examination based on the same is respectfully requested.

Claims 11-30 are pending in the instant Application.

The instant invention is directed to a cosmetic preparation comprising from 0.1-to-5, by weight, of a glycyrrhetic acid zinc salt, 0.1-to-5, by weight, of benzoyl peroxide, optionally 0.1-to-5, by weight, of one or more other antibacterial or antibiotic agents effective to inhibit and/or prevent the growth of bacteria, particularly where, when the one or more other antibacterial or antibiotic agents is/are present, the ratio of the amount of glycyrrhetic acid zinc salt-to-the amount of the other antibacterial or antibiotic agent is 10:90-to-90:10, and certain further auxiliaries and/or additives, useful for the production of, e.g., shampoos, hair lotions, foam baths, shower baths, creams, gels, lotions, alcoholic or aqueous/alcoholic solutions, emulsions, wax/fat compounds or stick preparations, and to a method for treating and/or preventing acne comprising administering the cosmetic preparation of Applicant's invention.

Claims 11-19 have been rejected under 35 USC 112, first paragraph, as the Specification does not specify an "amount effective of the claimed cosmetic composition to inhibit or prevent the growth of bacteria".

As a Patent is not intended to be a prescription for medical administration of any specific amount of anything, Applicant respectfully suggest that the amounts specified in amended Claim 11 (incorporating the amounts from now-canceled Claim 15, based on original Claim 5, with the deletion of the "effective..." language) and the Specification at page 4, lines 11 and 12, clearly provide guidelines for the ranges of the glycyrrhetic antibacterial agent in the cosmetic preparations according to the invention. In addition, Claim 17 and the Specification, at page 4, lines 25 and 26, suggest guidelines for the ranges of other antibacterial components optionally in such preparations, thus clearly providing the guidelines appropriate for topical preparations, effective to inhibit or prevent the growth of bacteria when appropriately administered by ordinary people who have different exposures, personal habits and are subject to different hormone changes

that may affect the acne experienced. In any case, as the Specification and Claims clearly do specify ranges for the amounts of active ingredients comprising the preparations of the instant invention, it is believed that the rejection is satisfied and overcome. The examiner is, therefore, respectfully requested to reconsider and withdraw this rejection.

Claims 11-20 have been rejected under 35 USC 112, first paragraph, as the Specification, "while being enabling for treatment, does not reasonably provide enablement for prevention of acne".

Applicants respectfully suggest that by providing for administering to the skin a preparation according to the instant invention for inhibiting or preventing the growth of bacteria causing acne, they are enabling the prevention of acne. Acne simply cannot develop under constant administration of anti-acne active ingredients. Reconsideration and withdrawal of the rejection is, therefore, respectfully requested.

Claims 11, 18 and 22 have been rejected under 35 USC 112, second paragraph, as indefinite, as the "glycyrrhetic acid derivatives of claims 11 and 22..., as well as the salicylic acid derivatives of claim 18 are not specifically defined."

Applicant's amendments to Claims 11, 18 and 22 are believed to satisfy and overcome this rejection, which is respectfully requested to be reconsidered and withdrawn.

Claims 11-18 and 20-29 have been rejected under 35 USC 102(b) as anticipated by U.S. Patent 6,294,186 B1 to Beerse *et al.*

United States Patent 6,294,186 B1 (Beerse *et al*) describes antimicrobial compositions, substantially free (less than 0.01%, by weight) of para-amino salicylic acid, and having a

pH of about 1-to-about 7, preferably about 1.5-to-about 5, more preferably about 2-to-about 4, which allegedly provide enhanced immediate, as well as desired residual anti-viral and antibacterial efficacy on the skin and on other surfaces against Gram negative bacteria, Gram positive bacteria, viruses (e.g., rhinoviruses, adenoviruses, rotaviruses, herpes viruses, respiratory syncytial viruses, coronaviruses, parainfluenza viruses, enteroviruses, influenza viruses, etc., particularly rhinoviruses), fungi, and immediate germ reduction upon use for household cleaning, personal care, hospital and industrial applications, comprising a safe and effective amount, preferably about 0.01-to-about 20, more preferably about 0.1-to-about 10, even more preferably about 0.25-to-about 5, most preferably about 1-to-5% of a benzoic acid analog, such as, preferably, salicylic acid, benzoic acid, and combinations thereof, a safe and effective amount of a metal salt, most preferably selected from dermatologically-acceptable chelates and salts of Cu, Fe, Sn and combinations thereof, and from about 50-to-about 99.99, preferably about 80-to-about 99.9, more preferably about 90-to-about 98, most preferably about 90-to-about 95% of a dermatologically-acceptable carrier (potentially selected from almost twelve columns of possible carrier compositions, including aqueous-based solutions, alcohol-based solutions [e.g., comprising an alcohol and an acid ester of the alcohol to establish equilibrium and stabilize the compositions], or emulsion carriers, preferably leave-on systems or products containing from about 1-to-about 90, preferably about 5-to-about 10% of a dermatologically-acceptable anionic, nonionic, zwitterionic, amphoteric or ampholytic surfactant, and possibly including thickeners, hydrophilic gelling agents, hydrophobically-modified celluloses, and mixtures thereof, lipophilic skin moisturizing agents/emollients, emulsifying surfactants, and other optional components, such as from about 0.0001-to-about 10, preferably 0.01-to-5, more preferably 0.05-to-2% of an antimicrobial or antifungal active, a desquamation active, an anti-acne active, an anti-wrinkle and/or anti-atrophy active, such as vitamin B_3 compounds or retinoids, anti-oxidants/radical scavengers, from about 0.1-to-about 10, preferably from about 0.5-to-5% of an anti-inflammatory agent, such as a steroidal or nonsteroidal agent, a

mixture of nonsteroidal agents, and natural anti-inflammatory agents, including those obtained as an extract by suitable physical and/or chemical isolation from natural sources [e.g., plants, fungi and by-products of microorganisms, such as from *Glycyrrhiza glabra*, including glycyrrhetic acid, glycyrrhizic acid, and derivatives thereof {e.g., salts and esters}], anti-cellulite agents, topical anesthetics, tanning actives, skin-lightening agents, sunscreen actives, thickening agents, detackifying agents, and the like), as well as methods of use for these compositions and antimicrobial products incorporating them, such as chewing gum, lozenges, cough drops, toothpaste, mouthwash, intranasal sprays, throat sprays, hand sanitizers, hard surface cleaners, liquid or solid dish or laundry detergents, floor waxes, and glass cleaners, and including methods of preventing and/or treating a common cold, associated respiratory disease, bacteria-related diseases, dandruff, acne and absenteeism.

While very broadly suggesting treatments for, *inter alia*, acne, the Beerse *et al* Patent does little more than include it among its extensive lists and reference incorporations, while concentrating on treating the hands, nose, and nasal canal of the human body that might have contacted or transmit viruses or bacterial-related diseases. Further, while in column 4, lines 45-47, the Patent implies that any combination of required or optional ingredients are encompassed within its invention, it varies from requiring compositions of a benzoic acid analog and a metal salt with a dermatologically-acceptable carrier only in column 47, lines 17-54, where it states that "Applicants have found that compositions which contain a benzoic acid analog and a dermatologically-acceptable carrier and which are essentially free of metal salts are also effective". It never teaches or fairly suggests compositions containing a glycyrrhetic acid zinc salt and benzoyl peroxide. In fact, benzoyl peroxide is not even mentioned, and the glycyrrhetic acid zinc salt is only generally included as "glycyrrhetic acid,... and derivatives thereof (e.g., salts and esters)" in the Patent and the five pages of

Corrections to it. Clearly, the reference neither discloses nor reasonably suggests the novel compositions of the instant invention.

The Examiner is respectfully requested to reconsider and withdraw this rejection.

Claims 19 and 30 have been rejected under 35 USC 103(a) as unpatentable over U.S. Patent 6,294,186 B1 to Beerse *et al* in view of U.S. Patent 6,468,509 B2 to Lapidot *et al.*

United States Patent 6,468,509 B2 (Lapidot *et al*) relates to stable compositions in the form of an oil, a gel, a solid stick, a lotion, a cream, a milk, an aerosol, a spray, a powder, a foam, a shampoo, a hair conditioner or lacquer, or a make-up, of sunscreen or other active ingredients that are regularly used in cosmetic compositions, comprising one or more sunscreen or other active ingredients confined in the same 0.01-to-100, preferably 0.1-to-10μ inert, preferably silica or organically-modified silica, sol-gel microcapsules or each in separate capsules, the hydrophilicity/hydrophobicity character and size (independent of the cosmetic vehicle, the composition preparation method, or the concentration of active(s)) of which may be controlled, which capsules encapsulate (in order to reduce or prevent contact between/among the sunscreen or other active compounds or other components [to avoid potential cross-reactivity], the packaging material [which could cause discoloration and/or decomposition of such packaging, or affect the encapsulated composition itself], and the skin [to prevent potential photoallergy, phototoxicity or other undesired reaction]) UVA- and/or UVB-absorbing compounds or other active ingredients in any desired ratio, further possibly comprising cosmetic adjuvants, other additives, physical sunblock active ingredients, α- and β-hydroxy acids, such as salycilic acid, glycolic acid, lactic acid, retinoic acid, and mixtures thereof, easily incorporated in any acceptable cosmetic vehicle, such as fatty

alcohols, fatty acids, fatty acid esters, fatty acid triglycerides, lanolin, natural or synthetic oils and waxes, water-in-oil (w/o) or oil-in-water (o/w) emulsions.

While the Lapidot *et al* Patent indeed broadly suggests microcapsules for encapsulating more than the sunscreen compositions to which it is focused, it does not specifically disclose or in any way suggest encapsulating the specific preparations of the instant invention or even remotely cure the deficiencies of the Beerse *et al* Patent, which itself neither discloses nor reasonably suggests the novel preparations of the instant invention. The combination of these references cannot, therefore, make the microencapsulated compositions of Applicant's invention obvious.

Reconsideration and withdrawal of this rejection is also respectfully requested.

Believing that the Application is, therefore, in condition for allowance, Applicants earnestly solicit such favorable action of the Examiner, and respectfully request that a timely Notice of Allowance be issued in the prosecution of this Application.

If any further questions do remain which may be resolved by a telephone interview, the Examiner is respectfully requested to telephone Applicants' undersigned Attorney.

Respectfully submitted,

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